

30 days, following the date of the determination;

(d) Within 60 days after the end of any probationary period, HCFA makes a final determination as to whether or not a State continues to meet the criteria described at §493.515 of this subpart and issues an appropriate notice (including reasons for the determination) to the State. This determination is based on the evaluation of any of the following—

(1) The most recent validation inspection(s) and review findings. In order for the State to continue to be exempt, it must meet the criteria in §493.519 of this subpart;

(2) Facility-specific data, as necessary, as well as other related information;

(3) Inspection procedures;

(4) Licensure or approval requirements.

(e) HCFA may remove its approval of a State laboratory program effective 30 days from the date that it provides written notice to the State of this proposed action if the State has not made improvements acceptable to HCFA during the probationary period.

(f) The existence of any validation review, probationary status, or any other action by HCFA does not affect or limit the conducting of any validation inspection.

(g) HCFA will cancel the approval of a State laboratory program if the State fails to pay the applicable fees as specified in §§493.645 and 493.646.

(h) If HCFA determines at any time that the continued approval of a State laboratory program poses an immediate jeopardy to the patients of the laboratories in that State, or such continued approval otherwise constitutes a significant hazard to the public health, HCFA may immediately withdraw the approval of that State laboratory program.

(i) HCFA will publish a notice in the FEDERAL REGISTER containing a justification of the basis for removing its approval of the State laboratory program.

(j) After HCFA withdraws approval of a State laboratory licensure program, the exempt status of licensed or approved laboratories in the State continues in effect for 60 days after the

laboratory receives notification from the State of the withdrawal of HCFA's approval of the program. HCFA may extend this period for an additional 60 days for a laboratory if it determines that the laboratory submitted an application for accreditation to an approved accreditation organization or an application to HCFA for the appropriate certificate before the initial 60-day period ends.

(k) HCFA may withdraw a State laboratory program's approval if the State refuses to take enforcement action against a laboratory in that State where HCFA determined it to be necessary. Laboratories that are in a State where program approval has been removed are subject to the same requirements and survey and enforcement processes applied to laboratories that are not exempt from meeting CLIA requirements.

(l) Any State that is dissatisfied with a determination to remove the approval of its laboratory program may request a reconsideration of that determination in accordance with part 488, subpart D of this chapter.

[57 FR 34014, July 31, 1992, as amended at 60 FR 20046, Apr. 24, 1995]

Subpart F—General Administration

SOURCE: 57 FR 7138 and 7213, Feb. 28, 1992, unless otherwise noted.

§ 493.602 Scope of subpart.

This subpart sets forth the methodology for determining the amount of the fees for issuing the appropriate certificate, and for determining compliance with the applicable standards of the Public Health Service Act (the PHS Act) and the Federal validation of accredited laboratories and of CLIA-exempt laboratories.

[60 FR 20047, Apr. 24, 1995]

§ 493.606 Applicability of subpart.

The rules of this subpart are applicable to those laboratories specified in §493.3.

[58 FR 5212, Jan. 19, 1993]